

Docket No. MIT5038USNP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Thomas C. May Confirmation no. 5892
Appln. No. : 10/808,764 Art Unit: 3775
Filed : March 25, 2004 Examiner: David W. Bates
Title : IMPLANTABLE CROSS-PIN FOR ANTERIOR CRUCIATE LIGAMENT REPAIR

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March 8, 2010
(Date of Transmission)

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Commissioner for Patents
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APPEAL BRIEF

I. Real Party in Interest

By virtue of an assignment recorded at reel/frame 021071/0562 this application is assigned to DePuy Mitek, Inc. which is a subsidiary of Johnson & Johnson, a New Jersey corporation.

II. Related Appeals and Interferences

None

III. Status of Claims

The Application contains claims 1 to 16 of which claims 1, 3, 5, 7 and 9 stand rejected and form the basis of the current appeal. The remaining claims, 2, 4, 6, 8 and 10 to 16, have been cancelled.

IV. Status of Amendments

No amendments were made after issuance of the Final Rejection. A listing of the claims without amendment was provided with the Response to the Final Office Action.

V. Summary of Claimed Subject Matter

Claim 1 defines an implantable cross-pin for use in an ACL repair procedure. It comprises an elongated member 10 having a proximal end 20, a distal end 40, and an outer surface with a nose member 50 extending out from the distal end of said elongated member, itself having a proximal end 55 and a distal end 60. An axial trough 70 in the elongated member extends through the outer surface and has a proximal end 72, a distal end 74, a bottom 75, opposed sides 77, an open top 79, and a passageway 80. A guide wire opening 62 sits in the distal end of the nose member concentric with the central longitudinal axis 11 of the elongated member. An interior tunnel 100 having a passage with an enclosed circular perimeter in the nose member extends from the guide wire opening into the trough such that the passage is in communication with the guide wire opening and the trough. The interior tunnel is obliquely oriented relative to the central longitudinal axis of the elongated member. A guide wire 120 is seated in the axial trough and extends through the interior tunnel and the guide wire opening. The cross-pin comprises a biocompatible material. (Specification pg. 2, line 25 to page 3, line 5; pg. 4, line 17 to pg. 6, line 5; pg. 7, lines 15 to 20; FIGS. 1 and 5)

VI. Grounds of Rejection to be Reviewed on Appeal

A. The improper rejection of claims 1, 3, 5, 7 and 9 under 35 U.S.C. §103(a) over U.S. Patent Publication No. 2005/0159812 to Dinger III et al. in view of U.S. Patent No. 5,211,647 to Schmieding.

VII. Argument

A. The improper rejection of claims 1, 3, 5, 7 and 9 under 35 U.S.C. §103(a) over U.S. Patent Publication No. 2005/0159812 to Dinger, III et al. in view of U.S. Patent No. 5,211,647 to Schmieding.

The Examiner has failed to articulate a logical reason why one of ordinary skill in the art at the time of the invention would seek to combine Dinger, III et al. with Schmieding and even if combined the alleged combination fails to reach the claimed invention.

Schmieding teaches an interference screw and placement sheath for fixing a bone-tendon-bone (BTB) graft in an ACL repair. In the repair, opposing tunnels are drilled into the femur and tibia. An ACL replacement graft is harvested from elsewhere in the body and comprises a length of tendon each end of which is affixed to a small block of bone. One of these bone blocks is affixed into the tunnel in the femur employing the interference screw taught by Schmieding. The

sheath is a tube with a cut-out portion of its wall at its distal end. The sheath is placed adjacent the graft with the cut-out portion facing the wall of the tunnel and the interference screw is then placed through the sheath. The sheath thus protects the graft from damage from the threads of the screw and the cut-out portion allows the threads to purchase into the bone of the tunnel. The sheath is then removed.

Dinger, III et al. teach an implant for receiving an ACL replacement graft. It is roughly analogous to one of the bone blocks on the graft of Schmieding. A graft of tendon is inserted into its bore 14 and held by sutures. The implant is then placed into a femoral tunnel with an interference screw.

If one of ordinary skill in the art sought to combine these teachings they would perhaps seek to employ the sheath of Schmieding to protect the graft from the threads of the interference screw, although even this would not be necessary with the graft safely received inside the implant. In a clear case of hindsight reconstruction of Applicants' claimed invention the Examiner has taken features from these two references and applied to them different functions than taught by the references in an attempt to identify a combination having each of the elements as claimed by Applicants. This amalgamation of features would not have been suggested to one of ordinary skill in the art at the time of the invention, only to one who later uses Applicants' specification as a road map, and even then it is hard to

see how anyone could see their way to the claimed invention in the fashion proposed by the Examiner. The features of the two references seem merely mapped onto the claimed invention without sufficient thought as to how one at the time of the invention would have arrived at such configuration.

The Examiner opines that the bore 14 in Dinger, III et al. is a guide wire opening. It is not. That is where the graft is retained. Dinger, III et al. lacks a guide wire. Then the Examiner opines that to protect the missing guide wire of Dinger, III et al. one of skill in the art would seek to combine the features of Schmieding to protect the guide wire, which is not actually there, in Dinger, III et al. The Examiner's logic makes no sense. Dinger, III et al. teach no guide wire passage and it would be contrary to common sense to so modify the graft retaining bore 14.

Even if the alleged combination were made it fails to reach the claimed invention. Schmieding does not teach a trough and a passage leading obliquely therefrom to a distal opening in the nose. It teaches merely a tube with a cut-out at its distal end. There is no trough and no oblique passage. There is a guide wire and it goes straight down the center of the tube, without passing through a trough or an oblique passage or even the cut-out. It is the screw threads which pass through the cut-out portion of the tube wall. The Examiner opines that the cut-out

of Schmieding corresponds to a trough. Applicants' trough is claimed to have a bottom. A cut-out has no bottom. Applicants claim a guide wire in the trough. If the trough of the alleged combination is the cut-out the rejection again fails as the guide wire of Schmieding does not go through the cut-out. In many ways, the alleged combination fails to reach the claimed invention.

Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness and request withdrawal of the rejection and passage of the application onto issue.

Respectfully submitted,

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Claims Appendix

1. An implantable cross-pin for use in an ACL repair procedure, comprising:
 - an elongated member having a proximal end, a distal end, and an outer surface;
 - a nose member extending out from the distal end of said elongated member having a proximal end and a distal end;
 - an axial trough in the elongated member extending through the outer surface, said trough having a proximal end, a distal end, a bottom, opposed ends, an open top, and a passageway;
 - a guide wire opening in the distal end of the nose member and concentric with the central longitudinal axis of the elongated member;
 - an interior tunnel having a passage with an enclosed circular perimeter in the nose member extending from the guide wire opening and extending into the trough such that the passage is in communication with the guide wire opening and the trough, the interior tunnel being obliquely oriented relative to the central longitudinal axis of the elongated member; and
 - a guide wire seated in the axial trough and extending through the interior tunnel and the guide wire opening;
 - wherein the cross-pin comprises a biocompatible material.
3. The cross-pin of claim 1, wherein the material is bioabsorbable.

5. The cross-pin of claim 3, wherein the bioabsorbable material is selected from the group consisting of PLA, PGA, and copolymers thereof.

7. The cross-pin of claim 1, wherein the proximal end of the cross-pin comprises an opening in communication with the proximal end of the trough.

9. The cross-pin of claim 1, wherein the nose member has a bullet shape.

Evidence Appendix

None

Related Proceedings Appendix

None